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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/484,895      01/18/00      HARRINGTON

J      5817-7G

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HM12/0329

EXAMINER
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NGUYEN, Q

ART UNIT	PAPER NUMBER
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1632

DATE MAILED:

03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/484,895

Applicant(s)

HARRINGTON ET AL.

Examiner

Anne M Beckerleg

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 58-116 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 58-92, 97, 113-116, drawn to a vector, a host cell and a library of cells comprising the same, classified in class 435, subclass 320.1.
- II. Claims 93-96 and 98-101, drawn to methods for activating an endogenous gene, identifying a gene in a cell, isolating cells in which a single exon gene has been activated and for expressing a transcript containing exon 1 of a gene, classified in class 435, subclass 455.
- III. Claims 102-109, drawn to methods for producing a gene product encoded by an endogenous cellular genomic gene, classified in class 435, subclass 69.1.
- IV. Claims 110-112, drawn to a recombinant protein, classified in class 530, subclass 350+.

**If Group I is elected** a further election of species is required.

Claims 72-75, 78-79, 87 and 92 directed to the following patentably distinct species: 1) vector of claim 58, 2) vector of claim 65, 3) vector of claim 67, 4) vector of claim 70, 5) vector of claim 71.

Claim 113 directed to the following patentably distinct species: 1) neomycin, 2) hypoxanthine phosphoribosyl transferase, 3) puromycin, 4) dihydroorotase, 5) glutamine

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synthetase, 6) histidine D, 7) carbamyl phosphate synthase, 8) dihydrofolate reductase, 9) multidrug resistance I, 10) aspartate transcarbamylase, 11) xanthine-guanine phosphoribosyl transferase, 12) adenosine deaminase.

Claim 114 directed to the following patentably distinct species: 1) hypoxanthine phosphoribosyl transferase, 2) thymidine kinase, and 3) diphtheria toxin.

**If Group II is elected** a further election of species is required.

Claims 93-96 directed to the following patentably distinct species: 1) vector of claim 58, 2) vector of claim 65, 3) vector of claim 67, 4) vector of claim 70, 5) vector of claim 71.

Claims 100-101 directed to the following patentably distinct species: 1) vector of claim 58, 2) vector of claim 59, 3) vector of claim 61, 4) vector of claim 65, 5) vector of claim 67.

**If Group III is elected** a further election of species is required.

Claims 102-109 directed to the following patentably distinct species: 1) vector of claim 58, 2) vector of claim 59, 3) vector of claim 61, 4) vector of claim 65, 5) vector of claim 67.

Claim 108 is directed to the following patentably distinct species: 1) BAC, 2) YAC, 3) PAC, 4) cosmid, 5) phage, 6) plasmid.

**If Group IV is elected** a further election of species is required.

Claims 110-112 directed to the following patentably distinct species: 1) a protein expressed by vector of claim 58, 2) a protein expressed by vector of claim 59, 3) a

protein expressed by vector of claim 61, 4) a protein expressed by vector of claim 65, 5) a protein expressed by vector of claim 67.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In the instant case, a vector of Group I can be used in any of the methods of Groups II and III.

Inventions I and IV are drawn to distinct products capable of separate uses. The vector of Group I can be used to as a probe in hybridization assays whereas the recombinant protein of Group IV can be used to produce antibodies.

Inventions II and III are drawn to different methods having different method steps, requiring different starting materials and different end-points.

Inventions II and IV are mutually exclusive and independent. The methods of Groups II are not required for the recombinant protein of Group IV, and vice versa.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the recombinant protein of Group IV can be made by standard recombinant cDNA expression.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

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a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Karen Hauda, at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.**

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-4242.

  
DAVE NGUYEN  
PRIMARY PATENT EXAMINER  
AU 1632